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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DRODGE, JOSEPH W

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,920

Applicant(s)

HARRAWAY, JAMES

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "having associated" is indefinite, since it is unclear if the text following recites subcomponents as being a part of the preceding component or merely operatively connected to such component.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 1, the "hydraulic flow element" is recited as being included within the "blood flow element"; however, page 4, lines 16-17 of the Instant Specification merely describes such hydraulic flow element as being "located behind" the "blood flow element". Inherently, such hydraulic flow element is for use with water/dialysis solution flow control, as is well known in the prior art (see Peterson et al and Zimmerman et al, already of record).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenley et al patent 5,788,851 in view of Lebel et al patent 6,577,899, Peterson et al patent 5,487,827 and Lichtenstein patent 4,370,983.

Kenley et al disclose a dialysis machine and user interface system (column 6, lines 9-13, etc.), comprising a blood flow element (column 5, lines 14-28) enclosure 26, removable base 28, front panel 12 that includes a touch panel element 14 (see column 6, lines 13-26), smart function keys 16, 18 and 20, and connectors (column 6, lines 27-35), a plurality of electronic circuit elements including driver and analog boards 112 and 114, water reservoir 23 or 25.

The claims all firstly differ in requiring a hydraulic flow element, interpreted from the Instant Specification as a component which is distinct from the blood flow element for flowing another fluid of the dialysis solution (i.e. "dialysis solution or water").

Peterson et al teach such hydraulic flow element in column 1, line 65-column 2, line 18 and column 3, lines 37-42. It would have been obvious to one of ordinary skill in the art, to have utilized a hydraulically controlled component(s) in formation and movement of dialysis/dialysate solution in the Kenley et al machine/system, as taught by Peterson et

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al, since hydraulically controlled components are readily adaptable to control by highly automated control equipment, as in Kenley et al or Peterson et al, and enable efficient deaeration of the dialysis fluid.

The claims also differ in requiring the touch panel to include a voice-activated sensor, i.e. include a voice-activation element to assist with controlling the device, generally. Lebel et al teach a touch panel interface and controlling module for an implantable infusion device to supplement key and touch element components (column 2, lines 34-59 and column 24, lines 31-67). Lichtenstein supports the teaching of Lebel et al for incorporating a touch screen/panel, since Lichtenstein teaches that dialysis machines/modules may be used interchangeably or together with a variety of other medical devices and modules including infusion device modules (column 2, lines 46-51 and column 5, lines 34-55), and in highly automated medical systems (see various portions of the Lichtenstein text). It would have been obvious to one of ordinary skill in the art to have supplemented the touch screen panel of Kenley et al with a voice-activated element, as suggested by Lebel et al taken with Lichtenstein, for increased safety to the patient being treated by the device and for enhanced interface convenience of an operator, technician, doctor or patient utilizing the dialysis system of Kenley et al.

Regarding claims 2 and 3, see column 7, line 55 through column 8, line 5 of Kenley et al concerning connections to remote controllers and displays by various communication links and the Internet.

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The claims also differ in requiring a power supply. However, Peterson et al teach such power supply with an automated dialysis system that includes a touch panel interface, which includes such power supplies (column 13, lines 32-49 and column 20, lines 15-23). It would have also been obvious to one of ordinary skill in the art to have included the power supplies of Peterson et al in the system of Kenley et al, to provide the forces needed for physical movement of blood being treated, dialysis solution and activation of the control and monitoring systems.

Regarding claim 4, Lichtenstein further teaches connection to and displaying of parameters associated with pulse, ECG and blood pressure monitoring devices (column 6, line 61 through column 7, line 18). It would have been further obvious to have included the pulse, ECG and blood pressure monitoring devices and associated respective displays taught by Lichtenstein, in the system of Kenley et al, so as to effect changes in operation of the dialysis treatment which are tailored to specific, unique, current, medical needs of the patient being treated.

Regarding claim 5, Peterson et al also teach the recited blood flow pump, flow path, venous and arterial chambers, ports, and connections, as well as associated transducers to monitor pressures and flow rates in various parts of a dialysis blood flow system, which have become well known to those of ordinary skill in the dialysis treatment art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al patent 5,487,827 of record.

Peterson et al disclose the claimed dialysis system including dialysis machine, automated controller and user interface system including touch screen element (column 8, lines 15-21), electronic circuit elements (see column 15, lines 39-67, especially the table encompassing lines 42-48), blood flow elements of pumps, dialyzer, arterial and venous chambers and connections (see especially column 11, lines 33-40 and column 13, lines 18-31), arterial and venous transducers for monitoring pressures and flow rates (column 11, lines 33-40).

JWD

July 21, 2003


JOSEPH D. DODGE
PRIMARY EXAMINER